Remarks

The Applicants have amended the Abstract in accordance with the Examiner's helpful suggestion and a copy of a new Abstract is enclosed on a separate sheet for the Examiner's convenience.

The "Brief Description of the Drawings" section has been amended in accordance with the Examiner's helpful suggestions and we respectfully submit that that portion of the Specification is now in proper form. Also, Fig. 6 has been amended to relabel the various sub-portions so that they begin with Fig. 6a. A copy of Fig. 6 is enclosed with the new designations for the Examiner's convenience. A formal Fig. 6 will be submitted, along with the remainder of the Figures, upon allowance of the Application.

The Specification has been amended on pages 6 and 7 in accordance with the Examiner's helpful suggestion to provide the proper SEQ ID No. and to recite the presence of an amino acid sequence.

Finally, the title has been amended in accordance with the Examiner's helpful suggestion. We respectfully submit that the Specification, Drawings, Abstract and Title are now in proper form. To the extent that any additional minor changes are deemed appropriate, the Applicants would appreciate the opportunity to discuss the matter by telephone with the Examiner.

The Applicants note with appreciation the Examiner's comments concerning the Information Disclosure Statement. We respectfully submit that the Information Disclosure Statement fully complies with the Rules. There is an explicit statement in the Information Disclosure Statement that the enclosed publications are believed related in view of their mention in the Search Report for the reasons stated therein. We enclose yet another copy of the Search Report for the Examiner's convenience. We respectfully submit that this clearly complies not only with the letter, but the spirit of the duty of disclosure rules. Confirmation of consideration of the publications is respectfully requested.

The Applicants note the Examiner's acknowledgment of the Claim of Priority. The certified copy of the priority application was filed on September 17, 2002. Confirmation of receipt of the certified copy is respectfully requested.

Claims 1 - 7, 10 - 30, 36 and 39 - 51 have been canceled as non-elected subject matter. Of course, the Applicants specifically reserve the right to file one or more divisional applications directed to the subject matter therein.

Claims 8 and 9 have been amended so that they are dependent on Claims 34 and 35, respectively, and we respectfully request that, in view of the change of their orientation from claiming a nucleic acid molecule to a method, they also be examined on the merits.

Claims 31 - 35 have been amended substantially in accordance with the Examiner's helpful suggestions with respect to additional steps with respect to transferring a purified nucleic acid sequence into a cellular host and culturing the host under conditions for expression. Claim 31 has also been amended to specify that the purified protein is a purified TRAAK channel protein. Support is clearly found throughout the Specification as originally filed. Claim 32 also recites that the transferred, purified nucleic acid sequence is the purified nucleic acid sequence or a functional equivalent derivative thereof. Support may be found at page 6 of the Specification, beginning at line 7. Accordingly, no new matter has been added. Also, by virtue of the definition set forth on page 6, beginning at line 7, we respectfully submit that one of ordinary skill in the art clearly understands what is meant by that additional language. Claim 33 specifies that the host is cultured under conditions for expression of TRAAK potassium channel exclusively in brain, cerebellum, spinal cord and retina neural tissues. Support may be found at page 14, line 17. Claim 34 has also been amended to recite that the purified nucleic acid sequence is represented by SEQ ID No: 1. Similarly, Claim 35 has been amended to recite that the purified nucleic acid sequence is represented by SEQ ID No: 2. Support is found throughout the Specification for these two SEQ IDs.

All of Claims 31 - 35 have been amended to substitute --selected-- for "varying." This simply means that one of ordinary skill in the art selects a particular amount of the substance to be screened and proceeds. This can be repeated as many times as desired with different selected amounts of the substance to be screened. Selected or varying amounts may also be seen by reference to Fig. 9b. Accordingly, when the Applicants tested the activation of the TRAAK channel by arachidonic acid, they used a range of concentrations from 0.01 to 100 μM.

With respect to the terms "activity" and "effect", these simply refer to the potassium currents. Thus, one of ordinary skill in the art readily understands that, when the modulation of the TRAAK channel is measured, the potassium current is tested. For example, we invite the Examiner's attention to Fig. 7, wherein activation of the TRAAK channel is achieved by stretching, and Fig. 9, wherein activation of the TRAAK channel is by polyunsaturated fatty acid. Accordingly, these are simple terms readily understood to those of ordinary skill in the art. As an example of ordinary such terms are, we enclose a copy of U.S. Patent 6,309,855 which, for example, utilizes activation and activities repeatedly, such as at Column 4 in the paragraph beginning at line 16. Also, use of the term "effect" is present in the '855 patent as well, such as at Column 8 in the paragraph beginning at line 27.

With respect to the enablement rejection of Claims 31 - 38, we respectfully submit that the amendments to Claims 34 and 35 (as well as the cancellation of Claim 36) render those rejections moot. With respect to the remaining claims, they have been amended to recite the purified TRAAK channel protein which is fully enabled. Thus, while the Applicants appreciate the Examiner's detailed comments concerning non-enablement, such as the fact that over 50 distinct channels have been identified in humans in both excitable and non-excitable cell types, those of ordinary skill in the art need not concern themselves with other distinct channels. They only need to concern themselves with the TRAAK channel, for which the Applicants have provided detailed guidance and a working example. We also invite the Examiner's attention to *Ex parte Forman*, 230 USPQ 546,

547 (Board of Appeals 1986), wherein the standard for determining enablement under 35 USC §112, first paragraph, is outlined as follows:

> The ultimate question in each case of this type is whether or not the specification contains a sufficiently explicit disclosure to enable one having ordinary skill in the relevant field to practice the invention claimed therein without the exercise of undue experimentation.

"Undue" experimentation can include very extensive amounts of experimentation. This fundamental test is:

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art: Ansul Co. v. Uniroyal, Inc., supra. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. In re Rainer, 52 CCPA 1593, 347 F.2d 574, 146 USPQ 218 (1965); In re Colianni, supra. 230 USPQ at 547.

In this case no "undue" experimentation is necessary to practice the invention as claimed herein. The specification provides an extremely detailed example concerning the TRAAK channel. Moreover, the state of the art is quite advanced, with high levels of skill, as evidenced by the prior art of record which discloses other types of channels in the form of the Fink reference, the Gubitosi-Klug reference and the enclosed 6,309,855 patent. One of ordinary skill in the art, having the inherent skill in the art and viewing the prior art, would be fully enabled to practice the subject matter as recited in those claims based on the guidance provided in the Applicants' Specification. The fact that experimentation is necessary does not constitute "undue" experimentation. Moreover, this art is notorious for the rather large amount of experimentation that is necessary. However, that large experimentation is ordinary, not undue. We therefore respectfully submit that the amendment to

Claims 31, 32 and 33 render those claims fully enabled. Withdrawal of the 35 U.S.C. §112 rejection is accordingly respectfully requested.

Turning now to the merits, the Applicants acknowledge the rejection based on the hypothetical combination of Fink with Gubitosi-Klug. In view of the amendment to Claims 34 and 35 with respect to SEQ IDs 1 and 2, we respectfully submit that, even if one of ordinary skill in the art were to make the hypothetical combination, the resulting method would still not teach or suggest what is claimed in Claims 34 and 35. Fink discloses the sequence of TREK-1, which is SEQ ID No: 4 in this Application. However, there are no teachings or suggestions with respect to either or both of SEQ IDs 1 and/or 2. Withdrawal of the 35 U.S.C. §103 rejection as it applies to Claims 34 and 35 is accordingly respectfully requested.

With respect to the remaining independent claims, we respectfully submit that they, too, are fully patentable over a hypothetical combination of Fink with Gubitosi-Klug. There are no teachings or suggestions whatsoever with respect to the claimed purified TRAAK channel protein. Careful scrutiny of both disclosures reveals that they do not disclose or teach the TRAAK channel protein nor do they suggest it. As a consequence, even if one of ordinary skill in the art were to make the hypothetical combination, the resulting combination would still fall far short of the invention as recited in independent Claims 31 - 33 and the claims depending therefrom. Withdrawal of the 35 U.S.C. §103 rejection is accordingly respectfully requested.

In light of the foregoing, we respectfully submit that the entire Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,

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